IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

(1) TULSA CANCER INSTITUTE, PLLC, an Oklahoma Professional Limited Liability Company; (2) OKLAHOMA ONCOLOGY & HEMATOLOGY, INC., an Oklahoma Corporation, dba CANCER CARE ASSOCIATES; (3) STATE of OKLAHOMA ex rel., BOARD of REGENTS for the STATE of OKLAHOMA; (4) TEXAS ONCOLOGY, P.A., a Texas Professional Association;	)	Case No. 15-CV-157-TCK-TLW Jury Trial Demanded
Plaintiffs,	)	
v.	)	
GENENTECH INC., a California Corporation,	)	
Defendant.	)	

SECOND AMENDED COMPLAINT

The Plaintiffs, collectively and individually, allege and state:

Jurisdiction and Venue

The Plaintiffs

1. Tulsa Cancer Institute, PLLC is an Oklahoma professional limited liability company with its principal place of business in Tulsa, Oklahoma.

2. Oklahoma Oncology & Hematology, Inc., is an Oklahoma corporation doing business as Cancer Care Associates with its principal place of business in Tulsa, Oklahoma.

3. The State of Oklahoma ex rel., Board of Regents of the State of Oklahoma acts for and on behalf of the University of Oklahoma Stephenson Cancer Center. The University of Oklahoma Stephenson Cancer Center's principal place of business is Oklahoma City, Oklahoma.

4. Texas Oncology, P.A., is a Texas professional association with its principal place of business in Dallas, Texas.

The Defendant

5. Defendant Genentech Inc. ("Genentech") is a Delaware corporation with its principal place of business in San Francisco, California.

Jurisdiction and Venue

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332 because there exists complete diversity among each Plaintiff and the Defendant and the amount in controversy, exclusive of interest and costs, exceeds $75,000.

7. The Defendant is subject to this Court's personal jurisdiction.

8. Venue is proper in the Northern District of Oklahoma pursuant to 28 U.S.C. §1391.

9. Plaintiffs Tulsa Cancer Institute and Oklahoma Oncology & Hematology reside in this judicial district.

10. Each Plaintiff conducts business in Oklahoma.

Summary of the Plaintiffs' Claims

11. Each of the Plaintiff organizations provide healthcare services and specialize in the diagnosis and treatment of cancer. Each of the Plaintiffs purchased a cancer treatment drug known as Herceptin which was manufactured and distributed by the Defendant Genentech. Each of the Plaintiffs suffered damages caused by Genentech's breach of warranties concerning the advertising, labeling and delivery of the true volume and density of Herceptin available in the vials Plaintiffs purchased.

12. Herceptin is distributed in containers (vials) which are represented by Genentech to contain 440 milligrams (mg) of lyophilized (dehydrated or "freeze-dried") medicine. To administer the medicine, the Herceptin product is mixed, pursuant to directions provided by Genentech, with a liquid (diluent), also provided to end users by Genentech. After mixing the lyophilized medicine and the diluent, Genentech claims the resulting fluid contains 440 mg of Herceptin at a concentration of 21 mg/mL.

13. 440 mg concentrated at 21 mg/mL would provide 20.952 mL of fluid solution.

14. Upon information and belief, the actual volume yielded for use in treating their patients is never more than 20.2 mL.

15. This shortage is caused either by a lower amount of Herceptin being provided than advertised or a higher concentration of Herceptin after mixing than advertised.

16. The 20.2 mL, rather than 20.952 mL, could be caused by Genentech providing 424 mg of Herceptin instead of the 440 mg represented and warranted by Genentech.

17. The 20.2 mL, rather than 20.952 mL, could be caused by Genentech inaccurately representing and warranting the concentration of the mixed fluid solution as 21 mg/mL when it really is 21.8 mg/mL.

18. Genentech's internal emails acknowledge that the represented concentration is not accurate. Genentech's Production Engineer explained to his internal audience that Genentech's own internal technical report showed a concentration of 21.8 mg/ml. *See* Email from Tom White to Olivia Ware and William Henry Smith (Sept. 25, 2002) (Ex. 1). However, Genentech made the calculated decision to represent the concentration as 21 mg/ml and thus require physicians and practice groups to buy more product.

19. Regardless the cause of the discrepancy, Plaintiffs do not receive 20.952 mL of fluid solution after following Genentech's direction despite paying for the 20.952 mL quantity.

The Plaintiffs

Tulsa Cancer Institute

20. At all times relevant to this action, Tulsa Cancer Institute was a physician-owned specialty medical practice that provided multidisciplinary care for patients with cancer and other blood disorders and is recognized for its clinical trials to evaluate new treatments conducted in collaboration with cancer patients. The clinical studies are regulated and approved by the United States Food and Drug Administration ("FDA") and are designed to find new drugs, new combinations of drugs, and/or innovative ways to treat cancer and improve the quality of patient care and outcomes.

Cancer Care Associates

21. At all times relevant to this action, Cancer Care Associates operated a blood and cancer disease organization treating patients under the trade name Cancer Care Associates, PC. In 2013, it closed its medical clinic and began operating as an administrative services organization, providing services to various medical practices on a contract basis.

The University of Oklahoma Stephenson Cancer Center

22. At all times relevant to this action, the Stephenson Cancer Center provided a comprehensive range of diagnostic and treatment options, specializing in almost every area of cancer treatment or research, including: medical oncology, radiation oncology, pediatric oncology, gynecological oncology, blood disorders and bone marrow

transplant. Cancers suffered by women are a special area of emphasis for OU Cancer Center. Five doctors, board-certified in gynecological oncology, are actively involved in medical research to find new and more effective treatments in the fight against female cancers.

Texas Oncology

23. Texas Oncology was founded in 1986 and at all times relevant to this action was a pioneer in community-based cancer care. It is an independent oncology practice with more than 375 physicians and 150 locations across southeastern Oklahoma and Texas, including 48 comprehensive cancer centers. Texas Oncology medical teams specialize in medical oncology, hematology, gynecologic oncology, pediatric hematology and oncology, and radiation oncology.

Factual Allegations (All Claims)

Herceptin's Purpose

24. The cancer drug that forms the basis for the claims in this lawsuit is Herceptin (trastuzumab). Herceptin is used to treat patients with metastatic breast cancer and tumors that overexpress the HER2 gene. Herceptin is widely-used and, with many patients, is an effective drug to reduce and deter the growth of malignant breast cells. Herceptin is approved by the FDA as an adjuvant therapy for breast cancer and for metastatic, gastric cancer which has tested positive for HER2 receptor sites.

25. The HER2 gene makes HER2 proteins, which are receptors on breast cells. Normally, HER2 receptors help control how a healthy breast cell grows, divides, and repairs itself. In about 25% of breast cancers, the HER2 gene fails to work correctly and makes too many copies of itself (known as HER2 gene amplification). The extra HER2 genes allow breast cells to make too many HER2 receptors; referred to as HER2 protein overexpression. This makes breast cells grow and divide in an uncontrolled way. Breast cancers with HER2 gene amplification or HER2 protein overexpression are called HER2-positive. HER2-positive breast cancers tend to grow faster and are more likely to spread and return after treatment compared to HER2-negative breast cancers.

26. Genentech manufactures and distributes Herceptin. Since 1998, Plaintiffs have purchased Herceptin, used in the treatment of their patients.

27. Genentech markets itself as a research-driven corporation. Genentech employs more than 1,100 researchers, who cover a wide range of scientific activity-from molecular biology to protein chemistry, bioinformatics and physiology. Genentech scientists claim to focus their efforts on five disease categories including oncology, immunology, tissue growth and repair, neuroscience and infectious disease.

28. Genentech markets and distributes Herceptin through a closed distributor network.

29. Herceptin is the only cancer medication currently on the market that effectively treats metastatic breast cancer and tumors that overexpress the HER2 gene.

Herceptin's FDA Approved Preparation Instructions

30. In 1998, Genentech submitted and the FDA approved a Label for Herceptin.

31. The 1998 FDA-approved Label provided a Preparation for Administration section that instructed: "Use appropriate aseptic technique. Each vial of HERCEPTIN should be reconstituted with 20mL of BWFI, USP, 1.1% benzyl alcohol preserved, as supplied, to yield a multi-dose solution containing 21 mg/mL Trastuzumab."

32. The FDA-approved Prescribing Information (or "Label") has been modified several times since 1998.

33. Each FDA-approved Prescribing Information for Herceptin included that same basic instruction, including the most recent April 2015 revised Prescribing Information: "Reconstitute each 440 mg vial of Herceptin with 20 mL of Bacteriostatic Water for Injection (BWFI), USP, containing 1.1% benzyl alcohol as a preservative to yield a multi-dose solution containing 21 mg/mL trastuzumab."

34. Herceptin is manufactured as a lyophilized (dehydrated and "freeze-dried" powder) medicine which is delivered in multi-dose vials, labeled by Genentech as containing 440 milligrams (mg) of Herceptin. The Herceptin product is mixed with a liquid (diluent), also provided to end users by Genentech. The mixing process is accomplished by injecting the diluent into the vial containing the lyophilized Herceptin. The typical single dose leaves other available medicine in the multi-dose vial, which most often is used as all or a portion of a dosage for a different patient.

35. This mixing process reconstitutes each vial of Herceptin into a multi-dose fluid solution.

36. Genentech represents and warrants that the resulting multi-dose fluid solution is concentrated at a density of 21 mg/mL.

37. 440 mg reconstituted into a fluid solution with a density of 21 mg/mL would result in 20.952 mL of fluid solution: 440 mg divided by 21 mg/mL.

The Herceptin Shortage

38. Plaintiffs have discovered that they cannot obtain 20.952 mL of fluid solution by following the Preparation of Administration instructions provided by Genentech and approved by the FDA. The discovery of this shortage was made more difficult because of

Genentech's decision to market Herceptin in multi-dose vials in the United States.

39. Plaintiffs never obtain more than 20.2 mL of fluid solution by following the Preparation of Administration instructions provided by Genentech and approved by the FDA.

40. These multi-dose vials were and are used by Plaintiffs to administer Herceptin to their patients based on each patient's prescribed treatment dosage.

41. Plaintiffs have evaluated laboratory testing performed on the reconstituted Herceptin. The laboratory testing determined, after the diluent provided by Genentech is mixed with the product, each vial yields no more than 20.2 mL of fluid solution rather than the 20.952 mL that is represented by Genentech's own warranties.

42. The reconstituted Herceptin does not contain 440 mg of Herceptin and/or is not a fluid solution with a concentration greater than 21 mg/mL.

43. Plaintiffs rely upon Genentech's representation that the concentration of the fluid solution is 21 mg/mL when administering the proper dosage to each patient. In administering the Herceptin from the multi-dose vials, Plaintiffs withdraw the amount of reconstituted Herceptin medicine necessary for each patient until each vial is emptied.

44. Relying on Genentech's representation that the fluid solution density is 21 mg/mL, Plaintiffs provide sufficient volume of the fluid solution to administer the proper dosage of Herceptin. For example, a person weighing 50 kg should receive 200 mg of Herceptin for her initial dose. To administer 200 mg of Herceptin, Plaintiffs would provide 9.52 mL of fluid solution: 200mg divided by 21 mg/mL.

45. If Genentech's representation that the fluid solution density is 21 mg/mL is accurate, then Genentech is providing, at most, 424 mg of Herceptin: 20.2 mL multiplied by 21 mg/mL. If Genentech is providing 424 mg or less of Herceptin, Genentech is providing less medicine than represented and warranted, and causing Plaintiffs to purchase additional Herceptin.

46. If Genentech's representation that the Herceptin vial contains 440 mg of Herceptin is accurate, then the fluid solution density is, at least, 21.8 mg/mL: 440 mg divided by 20.2 mL. If Genentech is providing instructions and product that create a fluid solution density of at least 21.8 mg/mL, Genentech is causing Plaintiffs to administer an overdose by representing the fluid solution density is 21 mg/mL, and causing Plaintiffs to purchase additional Herceptin.

47. Either way, Plaintiffs are forced to purchase additional Herceptin because following Genentech's Preparation of Administration

instructions yields less volume of fluid solution than mathematically follows from Genentech's representation and warranties.

First Claim - Breach of Express Warranty

Plaintiffs adopt the allegations contained in paragraphs 1 through 47 and further allege and state:

48. Beginning in 1998, Plaintiffs relied on all representations and warranties made by Genentech concerning the quantity of Herceptin purchased from Genentech.

49. Beginning in 1998, Plaintiffs relied on all representations and warranties made by Genentech concerning the density of the fluid solution of reconstituted Herceptin purchased from Genentech.

50. In Plaintiffs' experience, reconstituting each vial of Herceptin yields no more than 20.2 mL rather than the 20.952 mL that is represented by Genentech's own warranties.

51. Genentech's representations and warranties were material to Plaintiffs and were material to their purchase and use of Herceptin.

52. Genentech's false representations and warranties relied upon by Plaintiffs include:

a. Each vial purchased by Plaintiffs contains 440 mg of Herceptin.

b. Each reconstituted vial of Herceptin yields fluid solution with a density of 21 mg/mL.

c. Each reconstituted vial of Herceptin contains 20.952 mL of fluid solution.

53. As a result of Genentech's breach of express warranty, Plaintiffs have been and continue to be damaged due to the additional vials of Herceptin they were and are forced to purchase.

Second Claim - Breach of Implied Warranty

Plaintiffs adopt the allegations contained in paragraphs 1 through 53 and further allege and state:

54. Under the implied warranty of merchantability, Genentech was required to provide goods that were consistent in kind, quality, and quantity with the representations concerning the Herceptin product.

55. Genentech breached its warranty of merchantability by providing Plaintiffs with Herceptin that did not meet the quantity represented and warranted by Genentech.

56. As a result of Genentech's breach of implied warranty, Plaintiffs have been and continue to be damaged due to the additional vials of Herceptin they were and are forced to purchase.

Third Claim - Unjust Enrichment

Plaintiffs adopt the allegations contained in paragraphs 1 through 56 and further allege and state:

57. Genentech has received and continues to receive an unfair benefit through its practice of providing vials and product that yield only 20.2 mL of usable Herceptin fluid solution, but receiving payment for 20.952 mL of product for each vial sold.

58. Under the circumstances, as alleged herein, the retention of that benefit would unjustly enrich Genentech.

59. The Plaintiffs have suffered economic damages while Genentech has enjoyed unjust enrichment.

Request for Relief

WHEREFORE, Plaintiffs respectfully request the following relief:

1. Entry of a judgment for each Plaintiff against Genentech for all damages each has suffered through the date of judgment as a result of Genentech's activities and conduct;

2. Entry of a judgment for each Plaintiff against Genentech for its costs and attorneys' fees; and

3. All other relief as this Court may determine Plaintiffs are entitled to receive.

Respectfully Submitted,

/s/ Steven J. Adams

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ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of January, 2016, I electronically transmitted the foregoing document to the Clerk of the Court using the ECF System for filing and to the following ECF registrants:

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